REMARKS

Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 1, 3, 5, 7, 10, 12, 14, 17-20, 24, 27, 29-30 and 32 are currently amended, claims 9 and 33 are cancelled without prejudice or disclaimer, and new claims 34-35 are added. Claims 1, 3-8, 10-12, 14-32 and 34-35 are currently pending in this application.

Claim 1 is amended to specify that the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 170:1, and that the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the agent of interest is from about 1:1 to about 9:1. Support for the recited ranges of weight ratios is provided in Tables 1-7 of Examples 2-8. The following table lists the amount of the hydrodynamic fluid-imbibing polymer(s) (A), the amount of the hydrostatic pressure modulating agent (B), and the amount of the active agent (C) constituents listed in Examples 2-8, as well as the values of A/B and A/C, which have been calculated from the listed amounts of A, B and C in each example.

	Example Number						
Component (mg)	2	3	4	5	6	7	8
Hydrodynamic fluid-imbibing polymer(s) (A)	Carbopol® 971P (280 mg)	Carbopol® 971P (320 mg)	Carbopol® 971P and Carbopol® 934P (total = 180 mg)	Carbopol® 971P (171 mg)	Carbopol® 971P (171 mg)	Carbopol® 971P (203.7 mg)	Carbopol® 971P (200.5 mg)
Hydrostatic Pressure Modulating Agent (B)	Crospovi-done XL-10 (8 mg)	Crospovi-done XL-10 or INF-10 (6.4 mg)	Crospovi-done XL-10 or INF-10 (3.60 mg)	Crospovi-done XL-10 or INF-10 (3.60 mg)	Crospovi-done XL-10 or INF-10 (3.60 mg)	Crospovi-done XL-10 (1.54 mg)	Crospovi-done XL-10 (1.2 mg)
Active Agent (C)	Caffeine (70 mg)	Theophyl-line (80 mg)	Nifedipine (60 mg)	Diltiazem (60 mg)	Buspirone HCl (20 mg)	Ranitidine HCl (60 mg)	Tramadol HCl (200 mg)
A/B	35:1	50:1	50:1	47.5:1	47.5:1	132:1	167:1
A/C	4:1	4:1	3:1	2.8:1	8.6:1	3.4:1	1:1

Claims 3 and 12 are amended herein to replace the recitation "said hydrodynamic fluid-imbibing polymer" with the recitation —said one, or more than one hydrodynamic fluid imbibing polymer—, for consistency with claim 1. Claims 5, 7, 10, 12 and 18 are amended to replace the expression "said hydrostatic pressure modulating agent" with the expression —said one, or more than one hydrostatic pressure modulating agent— for consistency with claim 1. Claim 10 is further amended to delete the clause that specified the ratio of the hydrodynamic fluid-imbibing polymer to the hydrostatic pressure modulating agent.

Claim 14 is amended to replace the expression "said acrylic acid polymer" with the expression —said one, or more than one hydrodynamic fluid-imbibing polymer—. Claim 17 is amended to replace the expression "said polyglucan is selected" with the expression —said one, or more than one hydrodynamic fluid imbibing polymer is a polyglucan selected—. Claim 19 is amended to depend from claim 18 instead of claim 16. Claim 20 is amended to replace the expression "said rapidly swelling cross-linked cellulose derivative is selected" with the expression —said one, or more than one hydrostatic pressure modulating agent is a rapidly expanding cross-linked cellulose derivative selected—. Claims 24, 27, 29-30 and 32 are amended to more distinctly claim the subject matter for the sake of improved clarity. No new matter is added.

Support for new claims 34-35 is provided, for example, at page 17, line 15 to page 20, line 10 of the specification. No new matter is added. A change of address for the undersigned and an executed power of attorney by inventor accompanies this response.

REJECTION OF CLAIMS 12, 17, 20, 24, 29 AND 30 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 12, 17, 20, 24, 29 and 30 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

This rejection is respectfully traversed.

ANALYSIS

CLAIM 12

The Examiner alleges that claim 12 does not end with a period. Applicant respectfully submits that this rejection is obviated by the amendment of claim 12 to end the claim with a period.

CLAIM 17

The Examiner alleges that there is insufficient antecedent basis for the recitation "said polyglucan" in line 2 of claim 17, because claim 1 does not recite "polyglucan." Applicant respectfully submits that this rejection is obviated by the amendment of claim 17 herein, which replaces the recitation "said polyglucan is selected" with the recitation —said one, or more than one hydrodynamic fluid imbibing polymer is a polyglucan selected—.

CLAIM 20

The Examiner alleges that there is insufficient antecedent basis for the recitation "said rapidly swelling" in line 2 of claim 20, because claim 1 does not recite "rapidly swelling." Applicant respectfully submits that this rejection is obviated by the amendment of claim 20 herein, which replaces the recitation "rapidly swelling cross-linked cellulose derivative is selected" with the recitation —said one, or more than one hydrostatic pressure modulating agent is a rapidly expanding cross-linked cellulose derivative selected—.

CLAIM 24

The Examiner alleges that there is insufficient antecedent basis for the recitation "the dosage" in line 2 of claim 24, because claim 1 does not recite "dosage." Applicant respectfully submits that this rejection is obviated by the amendment of claim 24 herein, which replaces the recitation "the dosage form is" with the recitation —said hydrostatic delivery system is in the form of—.

CLAIMS 29 AND 30

The Examiner alleges that the inclusion of the modifier "type" in the recitation "matrix-type" in claims 29 and 30 makes the claims indefinite. Applicant respectfully submits that this rejection is obviated by the amendment of claims 29 and 30 herein, which replaces the recitation "matrix-type" with the recitation —matrix—.

In light of the above comments, the Examiner is respectfully requested to reconsider and withdraw the rejections against claims 12, 17, 20, 24, 29 and 30.

THE REJECTION OF CLAIMS 1, 3, 5, 24 AND 33 UNDER 35 U.S.C. § 102(b)

Claims 1, 3, 5, 24 and 33 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fritsch *et al.* (U.S. Patent No. 5,213,794) because Fritsch *et al.* allegedly

discloses a tablet formulation that includes a polyacrylic acid/methacrylate copolymer and polyvinyl-pyrrolidone, the combination of which the Examiner alleges is equivalent to the hydrostatic couple of the instant claims because of the inherent properties of the polymers that make up the tablet formulation.

This rejection is respectfully traversed.

RELEVANT LAW

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Spada*, 15 USPQ2d 1655 (Fed. Cir, 1990), *In re Bond*, 15 USPQ 1566 (Fed. Cir. 1990), *Soundscriber Corp. v. U.S.*, 360 F.2d 954, 148 USPQ 298, 301, adopted 149 USPQ 640 (Ct. Cl.) 1966. *See, also, Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913,1920 (Fed. Cir.), *cert. denied*, 110 S.Ct. 154 (1989). "[A]ll limitations in the claims must be found in the reference, since the claims measure the invention". *In re Lang*, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). Moreover it is incumbent on Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. *Lindemann Maschinen-fabrik Gmbh v. American Hoist and Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, the reference must describe the invention as claimed sufficiently to have placed a person of ordinary skill in the art in possession of the invention. An inherent property has to flow naturally from what is taught in a reference *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

THE CLAIMS

Claim 1 is directed to a hydrostatic delivery system that includes a hydrostatic couple and an agent of interest, where the hydrostatic couple includes one, or more than one hydrodynamic fluid-imbibing polymer, and one, or more than one hydrostatic pressure-modulating agent, where the hydrostatic pressure-modulating agent includes a hydrophilic cross-linked polymer, and where the agent of interest is released at a rate that is substantially concentration independent. Furthermore, the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 170:1, and the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the agent of interest is from about 1:1 to about 9:1. Claims 3, 5 and 24 depend from claim 1 and are directed to various embodiments thereof.

Disclosure of Fritsch *et al.*

Fritsch *et al.* discloses a composition comprising an antacid, calcium polycarbophil (a calcium salt of polyacrylic acid crosslinked with divinyl glycol), and crosprovidone (crosslinked polyvinylpyrrolidone) (see Example 1, column 6, lines 19-54). The compositions according to Fritsch *et al.* may be administered as chew tablets (see col. 5, line 33), or they are characterized by dissolving rapidly (see col. 5, lines 27-34 and col. 6, lines 50-54), and liberate granule particles that adhere to the gastric mucosa (e.g. col. 5, lines 10-16 and col. 6, lines 52-53). The weight ratio of calcium polycarbophil to crospovidone used in example 1 is about 3:1 (1,000 mg/343 mg), and the weight ratio of calcium polycarbophil to hydrotalcite is 1:1 (1,000 mg/1,000 mg).

ANALYSIS

Applicant respectfully submits that the rejection as applied to claim 33 is moot in light of cancellation of claim 33 herein.

Differences between the claimed subject matter and the disclosure of Fritsch *et al.*

The hydrostatic delivery system of the present invention is designed to produce a steady-state efflux, or a controlled release, of the agent of interest over a period of time (see page 23, lines 9-24; Figures 2-6) and a rate that is substantially concentration independent (see for example page 26, lines 29-31). The hydrostatic couple is defined within the specification, as comprising a hydrodynamic fluid-imbibing polymer (for example page 16, line10 to page 19, line 11) and a cross-linked hydrostatic pressure-modulating agent (for example page 19, line 13 to page 21, line 6). Applicant respectfully submits that Fritsch *et al.* does not teach or suggest a composition that includes an active ingredient in combination with one, or more than one hydrodynamic fluid-imbibing polymer, and one, or more than one cross-linked hydrostatic pressure-modulating agent, where the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 170:1, and where the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to said agent of interest is from about 1:1 to about 9:1.

It is respectfully submitted that the recited weight ratios of the components of the presently claimed system result in the active ingredient being released at a *controlled* rate that is substantially concentration independent, regardless of the nature of the active

agent. It is particularly pointed out that the weight ratios of the components used in Example 1 of Fritsch *et al.* do **not** result in a controlled release of the particles of the hydrotalcite active agent, but rather a rapid dispersion of these particles (see col. 6, lines 50-54).

Thus, Fritsch *et al.* does not disclose a hydrostatic delivery system that includes an active ingredient in combination with one, or more than one hydrodynamic fluid-imbibing polymer, and one, or more than one cross-linked hydrostatic pressure-modulating agent, where the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 170:1, and where the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to said agent of interest is from about 1:1 to about 9:1. Thus, Fritsch *et al.* does not disclose every element of claim 1 and claims depending therefrom. Therefore, Fritsch *et al.* does not anticipate any of claims 1, 3, 5, 24. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

REJECTION OF CLAIMS 1, 3, 5, 7, 8, 11, 12, 14, 15, 18, 20, 21, 24-29 AND 31-33 UNDER 35 U.S.C. §102(b)

Claims 1, 3, 5, 7, 8, 11, 12, 14, 15, 18, 20, 21, 24-29 and 31-33 are rejected under 35 U.S.C. § 102(b) as anticipated by Rork *et al.* (U.S. 5,582,838) because Rork *et al.* allegedly discloses every element of the delivery system claimed in claims 1-3, 5, 7, 8, 11-15, 20, 21, 24, 26-29, 31 and 32. The Examiner alleges that Rork *et al.* discloses a tablet formulation that includes an active ingredient, excipients such as polyvinyl-pyrrolidone and magnesium stearate, CARBOPOL polymer and carbonate, and alleges that the combination of polyvinylpyrrolidone and the CARBOPOL polymer is equivalent to the hydrostatic couple of the instant claims.

This rejection is respectfully traversed.

RELEVANT LAW

See related section above.

THE CLAIMS

See related section above.

Disclosure of Rork *et al.*

Rork *et al.* discloses a device that includes an inner core of two layers, one layer containing a beneficial agent and a polymer that forms microscopic beads when hydrated

surrounded by another layer of a polymer that forms microscopic beads when hydrated, and a water insoluble water impermeable polymeric coating applied to the core (col. 3, lines 30-43). Rork *et al.* discloses a composition comprising nifedipine, Carbopol 974P (a carboxypolymethylene prepared from acrylic acid crosslinked with allyl ethers of sucrose or pentaerythritol), and Providone K-90 (polyvinylpyrrolidone; see Example 2, column 13, lines 18-59), which is used as an excipient.

ANALYSIS

Applicant respectfully submits that the rejection as applied to claim 33 is moot in light of cancellation of claim 33 herein.

Differences between the claimed subject matter and the disclosure of Rork *et al.*

Rork *et al.* does not disclose a delivery system that includes an agent of interest, one, or more than one hydrodynamic fluid-imbibing polymer (e.g. Carbopol); and one, or more than one hydrostatic pressure modulating agent (e.g. crosslinked polyvinylpyrrolidone), where the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 170:1, and wherein the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to said agent of interest is from about 1:1 to about 9:1.

Thus, Rork *et al.* does not disclose every element of claim 1 or claims dependent thereon. Therefore, because Rork *et al.* does not disclose all elements of the claimed subject matter of claim 1 or claims dependent thereon, Rork *et al.* does not anticipate any of claims 1-3, 5, 7, 8, 11, 12, 14, 15, 18, 20, 21, 24-29, 31 and 32. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

REJECTION OF CLAIMS 4, 6, 9, 10, 16 AND 19 UNDER 35 U.S.C. §103(a)

Claims 4, 6, 9, 10, 16 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rork *et al.* (US 5,582,838) because the Examiner alleges that it would have been obvious to one of ordinary skill in the art to adjust the amounts of polymer to achieve the desired swelling for drug delivery or the amount of carbonate to include in the formulation or the particle size to be used in the formulation.

This rejection is respectfully traversed.

RELEVANT LAW

Under 35 U.S.C. §103, in order to set forth a case of prima facie obviousness the differences between the teachings in the cited reference must be evaluated in terms of the

whole invention, and the prior art must provide a teaching or suggestion to the person of ordinary skill in the art to have made the changes that would produce the claimed product. *See, e.g., Lindemann Maschinen-fabrik Gmbh v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 U.S.P.Q.2d 481, 488 (Fed. Cir. 1984). The mere fact that prior art may be modified to produce the claimed product does not make the modification obvious unless the prior art suggests the desirability of the modification. *In re Fritch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); see, also, *In re Papesh*, 315 F.2d 381, 137 U.S.P.Q. 43 (CCPA 1963).

In addition, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Further, that which is within the capabilities of one skilled in the art is not synonymous with that which is obvious. *Ex parte Gerlach*, 212 USPQ 471 (Bd. APP. 1980). Obviousness is tested by "what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981), but it cannot be established by combining the teachings of the prior art to produce the claimed subject matter, absent some teaching or suggestion supporting the combination (*ACS Hosp. Systems, Inc. v Montefiore Hosp.*, 732 F.2d 1572, 1577. 221 USPQ 329, 933 (Fed. Cir. 1984)). "To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher" *W.L. Gore & Associates, Inc. v. Garlock Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

THE CLAIMS

Claims 4, 6, 9, 10, 16 and 19 depend ultimately from claim 1, and are directed to embodiments thereof. Claim 1 is discussed in the related section above.

TEACHINGS OF THE CITED ART

Rork *et al.*

See related section above.

ANALYSIS

It is respectfully submitted that the Examiner has failed to set forth a case of prima facie obviousness for the following reasons.

(1) There would have been no motivation to have modified the teachings of Rork *et al.*

The cited reference must provide a teaching or suggestion to the person of ordinary skill in the art to have made the changes that applicant has done that would produce the claimed product. Rork *et al.* does not teach or suggest a hydrostatic delivery system that includes an active ingredient, one, or more than one hydrodynamic fluid-imbibing polymer, and one, or more than one cross-linked hydrostatic pressure-modulating agent as described above and as claimed in claim 1.

Rork *et al.* teaches that the rate of release of a beneficial agent from its composition is determined by the selection of the size and number of apertures through its water-impermeable coating, which subsequently expose the surface of the core to the environment (col. 11, lines 52-55). There is no teaching or suggestion that a controlled release of an agent of interest could be achieved by eliminating the water impermeable coating of Rork *et al.*, nor is there any guidance for selecting a combination of ingredients that when combined in a drug delivery system will release an agent of interest at a rate that is substantially concentration independent. Rork *et al.* does not teach or suggest a crosslinked polyvinylpyrrolidone and provides no motivation for substituting a crosslinked polyvinylpyrrolidone for any ingredient in its formulation, nor suggest any desirability of such a modification.

(2) Notwithstanding the lack of motivation, modification of the teachings of Rork *et al.* does not result in the instantly claimed delivery system.

As discussed above in the traverse of the rejection under §102(b), Rork *et al.* does not teach or suggest a composition, which includes an active ingredient one, or more than one hydrodynamic fluid-imbibing polymer (e.g. Carbopol); and one, or more than one hydrostatic pressure modulating agent (e.g. crosslinked polyvinylpyrrolidone), wherein the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the one, or more than one hydrostatic pressure modulating agent is from about 35:1 to about 170:1, and wherein the weight ratio of the one, or more than one hydrodynamic fluid-imbibing polymer to the agent of interest is from about 1:1 to about 9:1. Rork *et al.* does not teach or suggest a composition that releases an agent of interest at a rate that is

substantially concentration independent. Thus, Rork *et al.* does not teach or suggest every element of the subject matter of claim 1. Applicant respectfully submits that claims 4, 6, 9, 10, 16 and 19 depend from claim 1 and therefore include the limitations thereof. Therefore, Rork *et al.* does not teach or suggest every element of the subject matter of claims 4, 6, 9, 10, 16 and 19.

It is respectfully submitted that the Office Action does not set forth a case of *prima facie* obviousness. The Examiner has not shown that the reference teaches or suggests to the person of ordinary skill in the art to make the changes that would produce the claimed subject matter, nor that such modification would result in all the elements of the claimed subject matter. The Examiner is respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. §103(a) against claims 4, 6, 9, 10, 16 and 19.

Inadvertent Typographical Error in Response Mailed December 16, 2003

The Examiner requests that the applicant address the Cook *et al.* anticipatory or lack of anticipatory argument raised in the remarks and the argument of the Response mailed December 16, 2003. Applicant respectfully submits that the recitation "Cook *et al.*" was introduced in error, and does not represent a document that is relevant to the patentability of the subject matter of the present application.

* * *

In view of the above, examination of the application on the merits and allowance is respectfully requested.

Respectfully submitted,

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